

REMARKS

Claims 1-9 and 14-19 are pending and under consideration. Claims 1 and 14 are amended as described herein.

The drawings are objected to for the reasons set forth on the PTO Form 948 dated March 22, 2003. Specifically, Figures 1A, 1B and 7A-8C are objected to as containing lines, numbers and letters that are not of uniform thickness and well defined, clean, durable and black. Figures 1A, 1B and 8B are objected to as containing shade lines that are pale, rough and blurred. Figures 1A, 1B, and 7A-8C are objected to as containing numbers, letters and reference characters of less than 1/8 inch in height.

Claims 2, 5 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 3, 4, 6-9, 14 and 17-19 are rejected under the first paragraph of 35 U.S.C. § 112 as failing to satisfy the written description requirement.

For reasons set forth below, Applicants respectfully request that the rejections be removed and the claims be allowed to issue.

I. The Drawings Comply with 37 C.F.R. § 1.84

The drawings are objected to for the reasons set forth on the PTO Form 948 dated March 22, 2003. Specifically, Figures 1A, 1B and 7A-8C are objected to as containing lines, numbers and letters that are not of uniform thickness and well defined, clean, durable and black. Figures 1A, 1B and 8B are objected to as containing shade lines that are pale, rough and blurred. Figures 1A, 1B, and 7A-8C are objected to as containing numbers, letters and reference characters of less than 1/8

inch in height.

In response, Applicants submit herewith replacements of Figures 1A, 1B, 7A, 7B, 7C, 7D, 7E, 7F, 8A, 8B, and 8C. Applicants respectfully request that the Examiner now remove the objections to the drawings.

II. The Claims Satisfy the Written Description Requirement of 35 U.S.C. § 112, first paragraph

Claims 1, 3, 4, 6-9, 14 and 16-19 are rejected under the written description requirement of the first paragraph of 35 U.S.C. § 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner contends that there is insufficient written description for the *mda-7* promoter to support claims drawn toward nucleotide sequences that are at least 80% identical to the *mda-7* promoter of SEQ ID NO:1 and having defined functional characteristics. The Examiner further states that, while the claims are limited to a defined structure and function, the disclosure does not provide a correlation between the structure and function to which the claims are limited.

Citing the 2001 Guidelines for the Examination of Patent Applications Under 35 U.S.C. §112, the Examiner states that, with regard to relevant identifying characteristics, the Guidelines provide that claimed subject matter identified by structural and functional limitations must be supported by a known or disclosed correlation between function and structure. The Examiner concludes that, in the instant case, the skilled artisan would not expect that all nucleic acid sequences that meet the structural limitations of the claims would have the recited function, and it would not be apparent from the teachings of the specification and prior art which of the nucleic acids encompassed by the structural limitations would also have the functional characteristics of the

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claimed promoter.

Applicants respectfully traverse the rejection of Claims 1, 3, 4, 6-9, 14 and 16-19 under the written description requirement of the first paragraph of 35 U.S.C. § 112. Regarding the 2001 Guidelines, Applicants note that

[a]n applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics⁴², which provide evidence that applicant was in possession of the claimed invention,⁴³ *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.⁴⁴ *Federal Register* Volume 66, No. 4 at 1106, emphasis added.

Footnote 42 indicates that

[f]or some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. *Federal Register* Volume 66, No. 4 at 1110, emphasis added.

Applicants assert that the recitation of 80% sequence identity is a "relevant identifying characteristic," namely a structural parameter, of the molecules being claimed. Applicants further assert that 80% identity is a physical property of the claimed molecules.

Applicants disagree with the contention that it would not be apparent from the teachings of the specification and prior art which of the nucleic acids encompassed by the structural limitations would also have the functional characteristics of the claimed promoter. Applicants maintain that, to the contrary, the specification provides detailed guidance as to how one of ordinary skill in the art could evaluate nucleic acids with 80% identity to SEQ ID NO:1 to determine whether they fell within the scope of Claim 1. For example, the experiments disclosed in Figure 1 and described on p. 45 of the instant specification teach one of ordinary skill how to generate and test constructs comprising various candidate promoters having 80% identity to SEQ ID NO:1 for the functional characteristics that define the nucleic acids being claimed. For these reasons, Applicants respectfully

traverse the rejection of Claims 1, 3, 4, 6-9, 14 and 16-19 under the first paragraph of 35 U.S.C. § 112.

However, in the interest of furthering the prosecution of this case and to bring greater clarity to the claims, Applicants have amended Claims 1 and 14. As amended, Claims 1, 14, and the claims dependent therefrom are directed toward isolated nucleic acid molecules that specifically hybridize to the core promoter sequence of SEQ ID NO:1 in a Southern hybridization performed under stringent conditions, and that direct transcription in HO-1 or MeWo melanoma cells exposed to interferon β and mezerein.

The specification expressly defines the nucleic acid sequence of one embodiment of the *mda-7* promoter (SEQ ID NO:1), and indicates that other embodiments of the promoter would include those molecules with substantial homology to the *mda-7* sequence of SEQ ID NO:7, provided that they retain the critical functional characteristics of the *mda-7* promoter. Substantial homology is defined on page 15 of the specification as hybridization in a Southern hybridization performed under stringent conditions. Applicants invite the Examiner's attention to the instant specification at page 15, lines 27-33, which states:

DNA sequences that are substantially homologous can be identified in a Southern hybridization[,] experiment under, for example, stringent conditions, as defined for that particular system. Defining appropriate hybridization conditions is within the skill of the art. See, e.g., Sambrook et al., *supra*; DNA Cloning, vol I & II, *supra*; Nucleic Acid Hybridization, *supra*.¹

Thus, the specification refers to treatises more than ten years old as references for the standard laboratory technique of nucleic acid hybridization under stringent conditions.

Because the amended claims are supported by the specification, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 3, 4, 6-9, and 16-19 under the first

paragraph of 35 U.S.C. § 112.

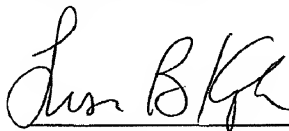
CONCLUSION

Based on the foregoing remarks and in light of the amendments, Applicants submit that the present application is in condition for allowance. A Notice of Allowance is therefore respectfully requested. Applicants note that this response is filed within two months of the mailing of the final rejection, pursuant to MPEP 714.13.

Applicants believe that no fees are due in conjunction with this timely-filed response. Should any fees be required, the Commissioner is hereby authorized to charge Deposit Account Number 02-4377. A duplicate copy of this communication is enclosed.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lisa B. Kole", written over a horizontal line.

Lisa B. Kole
Patent Office Reg. No. 35,225

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Enclosure

¹ Sambrook, Fritsch & Maniatis, Molecular Cloning: A Laboratory Manual, Second Edition (1989); DNA Cloning, Vols. I and II (D.N. Glover ed. 1985); Nucleic Acid Hybridization (B.D. Hames & S.J. Higgins eds. 1984)
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